UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,821	09/01/1999	MICHAEL J. WARING	CV0244	5635

26079 7590 01/15/2010

CONVATEC INC.
100 HEADQUARTERS PARK DRIVE
SKILLMAN, NJ 08558

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
01/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/341,821
Filing Date: September 01, 1999
Appellant(s): WARING ET AL.

John M. Kilcoyne
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 19,2009 appealing from the Office action mailed February 19, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

This application was previously appealed. Decision in Appeal No. 2006-2797.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

EP 666081	Court et al.	08-1995
US 3,788,521	Laauwe	01-1974
US 3,976,223	Jass et al.	08-1976

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 5, 6, 8-10, 14, 15, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of EP 0 666 081 (‘081), US 3,788,521 (‘521) and US 3,976,223 (‘223).

EP '081 teaches gel wound dressing comprising material comprising:

a) from about 0.05% to 10% by weight of natural gelling agent;

b) from about 1.0% to 10% by weight of hydrocolloid;

c) from about 5.0% to 30.0% by weight of an alkylene glycol and

d) at least 50% by weight of water.

Therefore, EP ‘081 teaches the gel wound dressing composition as claimed by claim 5. The gel composition of the reference can be extruded in the form of gel through

a nozzle (page 2, lines 20-24; page 3, lines 14-18). The gel of the reference has viscosity of 50-800 Pas, as required by claim 18, (page 2, lines 54-55). The reference disclosed the gel conforms readily to the shape of the wound particularly when the wound includes a cavity, and that teaching suggests treating wound of sinus cavities (page 2, lines 8-9). The wound dressing is packaged and sterilized, as required by claims 6, 10 and 15.

Although EP '081 teaches delivery of gel wound dressing from a nozzle, it does not teach delivery of the gel wound dressing from aerosol barrier.

US '521 teaches pressurized aerosol package comprises rigid container having dispensing valve, and collapsible container inside the rigid container and pressurized gas, i.e. positive pressure, filled in between the two containers (abstract; col.3, lines 33-40, figures). The pressurized container is self-sealing according to applicants' definition to self-sealing in page 2, lines 14-21: "because there is positive pressure in the container, the vessel can be made self sealing. This aids maintenance of product sterility". The aerosol package is made large enough to provide multiplicity of one-shot applications (col.10, lines 43-44), i.e. multi-doses. Therefore, the pressurized aerosol disclosed by the reference is self-sealing and provides sterile multiple doses. Applicants disclosed at page 3, lines 34-36 that the aerosol vessel disclosed by US '521 is one of the preferred aerosol vessel used to deliver the gel of the present invention. US '521 teaches that the discharged product from the aerosol has a uniform density and maintained a predetermined physical characteristic all the life of the package (col.7, lines 47-52; col.10, lines 35-38). US '521 disclosed method for assembling the package

including the steps of filling the outer container with a gas, filling the inner container with the product, followed by inserting a valve on the neck of the containers with a press fit (col.12, lines 41-53).

However, US '521 does not teach delivering gel from the disclosed aerosol package.

US '223 teaches an aerosol container containing gel comprising carboxymethyl cellulose, gelling agent and alginate. The gel comprises polyethylene glycol, which reads on gelling agent and alkylene glycols claims by claim 5 (col.6, lines 28-31, 34, 48, 63-65; col.7, lines 29-30; col.9, lines 20-23, 45-48, 51-55). The aerosol containing gel used to treat burns, which reads on wound (col.9, lines 20-55). Therefore, the art recognized at the time of the invention that wound dressing gel can be delivered from an aerosol package. The aerosol is provided by mechanical stream break up features, i.e. self-sealing (col.2, lines 65-67). The aerosol disclosed by the reference is not a single dose container as implied by the effort made to avoid contamination of the contents during use.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound dressing gel deliverable from a nozzle for treating cavities comprising natural gelling agent, hydrocolloid, alkylene glycol and water as disclosed by EP '081, and one having ordinary skill in the art knowing that wound dressing gels can be delivered from an aerosol package as disclosed by US '223 would have been motivated to replace the delivery means that have a nozzle with an aerosol package, and further use the aerosol package disclosed by US '521 having inner and

outer container separated by pressurized gas, motivated by the teaching of US ‘521 that the discharged product from such as aerosol has a uniform density and maintained a predetermined physical characteristic all the life of the package, with reasonable expectation of having wound dressing gel delivered from an aerosol package having inner container and outer container separated by a pressurized gas and meanwhile the delivered gel will have a uniform density and maintain a predetermined physical characteristic all the life of the package.

The combined teaching of the references implies method of delivery of the wound dressing gel into the wound as required by claim 15.

Regarding claims 6, 9, 10, 15, 19 and 20 that require sterilization of the gel, it is obvious to one having ordinary skill in the art at the time of the invention to sterilize any wound dressing before application to the wound to avoid contamination of the tissue already compromised by the existing wound, with reasonable expectation to accomplish the step of sterilization of the gel composition prior or after loading into the aerosol container to obtain barrier aerosol containing sterile gel that can be applied safely to the tissue without pain with avoidance of contamination of tissue already compromised by the wound or burn. Additionally, the content of the pressurized aerosol disclosed by US ‘521 is expected to maintain sterility of its contents if it is sterilized because according to applicants' definition to self-sealing in page 2, lines 14-21: “because there is positive pressure in the container, the vessel can be made self sealing. This aids maintenance of product sterility". Therefore, pressurized aerosol container maintains the sterility of its content after each discharge due to the positive pressure.

Regarding claim 14 that teaches treating sinuses, one having ordinary skill in the art will be motivated to use the gel composition delivered by aerosol of the combined teachings of the references to treat sinuses because EP '081 suggested delivering the wound dressing gel to the body cavities, and that encompasses sinuses cavities, and one having ordinary skill in the art would have been motivated to use the aerosol because US '223 teaches aerosol gel is protected from contamination, and US '521 teaches that products delivered from pressurized aerosol will have a uniform density and maintain a predetermined physical characteristic all the life of the package.

(10) Response to Argument

Appellant's arguments filed 08/19/2009 have been fully considered but they are not persuasive.

Appellants argue that while '081 does disclose a gel, '081 does not disclose a method of, and a vessel for, safely and efficiently dispensing multiple doses of wound-treating gel where the gel is in gel form in the container, and the vessel's self-sealing characteristic minimizes the contamination of the gel after the use of the vessel.

Appellants argue that '223 is cited to show an aerosol container containing a gel, However, the purpose of the package of '223 is to separately store a plurality of flowable substances in a single package from which such substances may be dispensed. According to '223, only the lower chamber of the outer container is pressurized with a gas through a self-sealing plug in the container bottom, therefore, the container in '223 is not self-sealing as required in the rejected claims. Moreover, '223 does not address

the avoidance of contamination during use, rather, avoidance of contamination appears to be with respect to storage.

Appellants argue that the addition of '521 does not make up for the deficiencies of the other two documents. It is cited in the specification as showing one example of the general "type" of vessel used. However, as noted in the rejection, '521 does not teach delivering a gel. The problem addressed by '521 concerns overrun which means that the amount of product dispensed varies as the container empties, and often product remains in the container that cannot be dispensed. Appellants' invention is concerned with packaging a gel so that the packaging can be used to dispense more than one dose without compromising the sterility of the remaining doses. One of ordinary skill in the art at the time the invention was made did not put wound gels in barrier aerosol containers and would not look to the hair coloring/shaving cream art of '521.

In response to the above arguments, it is argued that the present invention as a whole as defined by the claims would have been prima facie obvious in view of the combination of the cited prior art. The claimed gel composition is disclosed by EP ‘081. The only difference between the reference and the present claims is the packaging of the gel composition and its delivery from an aerosol. EP ‘081 suggests gel extruded from a nozzle. EP ’081 disclosed the gel composition is sterilized and autoclaved without destruction. The gel disclosed by EP ‘081 is multi-doses and sterile. Multi-doses also taught by US ‘521 at col.5, lines 37-57, wherein the reference stated: “The new package has a great advantage that the discharge product is of uniform consistency

and density through out the life of the package, even when **used intermittently during a long time period**…". The pressurized container is self-sealing according to applicants' definition to self-sealing in page 2, lines 14-21: "because there is positive pressure in the container, the vessel can be made self sealing. This aids maintenance of product sterility". The aerosol package according to US '521 is made large enough to provide multiplicity of one-shot applications (col.10, lines 43-44), i.e. multi-doses. Therefore, the pressurized aerosol taught by US '521 is self-sealing and provides sterile multiple doses.

US '223 is relied upon for teaching gel can be delivered to wound or burn from a pressurized aerosol container. US '223 is interested in making gel in aerosol for spraying. US '223 solved problem of keeping reactive components that may interfere with one another prior to application apart until dispersion from the container. It necessary follows from the teaching of EP '081 and US '223 that one would use single compartment vessel when there was no issue of reactivity or degradation of components of the composition. The aerosol containing gel taught by US '223 is used to treat burns, which reads on wound (col.9, lines 20-55). Therefore, the art recognized at the time of the invention that wound dressing gel can be delivered from an aerosol package. The aerosol is provided by mechanical stream break up features, i.e. self-sealing (col.2, lines 65-67). The aerosol disclosed by US '223 is not a single dose container as implied by the effort made to avoid contamination of the contents during use.

Hence, US ‘521 was involved in the rejection for teaching aerosol container having single inner and single outer container separated by pressurized gas, because US ‘521 teaches that the discharged product from such as aerosol has a uniform density and maintained a predetermined physical characteristic all the life of the package. US ‘521 teaches the aerosol vessel taught by applicants. US ‘521 teaches multi-doses at col.5, lines 37-57, wherein the reference stated: “The new package has a great advantage that the discharge product is of uniform consistency and density through out the life of the package, even when **used intermittently during a long time period**…”. EP ‘081 teaches sterile gel and if to be packaged in the aerosol of US ‘521, then it will be sterile.

Appellant further argue that actual teaching of US '223 is inapplicable to the claims because the purpose of the package of '223 is to separately store a plurality of flowable substance in a single package from which such substances may be dispensed. To say that "[I]t necessary (sic) follows from the teaching of EP '081 and US '223 that one would use (sic) single compartment vessel when there was no issue of reactivity or degradation of components of the composition" guts the whole teaching of US '223. While it may be "proper to take into account not only the specific teachings of the references but also the inferences which one skilled in the art would reasonably be expected to draw therefrom", one cannot gut the actual teachings of the references to combine them for some superficial notion. It cannot be casually argued that the rational

to combine teachings "may be expressly or impliedly contained in the prior art; when the rational is neither.

In response to this argument, it is argued that US ‘223 states that the "relative metering" of the flowable material from the container "is constant throughout the life of the dispenser," indicating that it contains "multiple doses," as required by claim 1, col.4, line 66-col.5, line 2. US ‘223 is relied upon for teaching that gel composition comprising carboxymethyl cellulose, gelling agent and alginate can be delivered to wound/burn using aerosol container. US ‘521 teaches single compartment container.

In response to the argument that the rational to combine EP ‘081 and US ‘223 not expressly or impliedly contained in the prior art, it is argued that the claimed gel composition is taught by EP ‘081 and US ‘223 is relied upon for teaching gel can be delivered from a pressurized aerosol container. US ‘223 is interested in making gel in aerosol for spraying. US ‘223 solved problem of keeping reactive components that may interfere with one another prior to application apart until dispersion from the container. It necessary follows from the teaching of EP ‘081 and US ‘223 that one would use single compartment vessel when there was no issue of reactivity or degradation of components of the composition since the components of the composition are taught by EP ‘081 as combined into one composition and no reaction between the components was disclosed. The aerosol containing gel taught by US ‘223 is used to treat burns, which reads on wound (col.9, lines 20-55). Therefore, the art recognized at the time of the invention that wound dressing gel can be delivered from an aerosol package. The aerosol is provided by mechanical stream break up features, i.e. self-sealing (col.2,

lines 65-67). The aerosol disclosed by the reference is not a single dose container as implied by the effort made to avoid contamination of the contents during use. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). It further has been held that omission of an element and its function is obvious if the function of the element is not desired. *Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975). Therefore, the rational to combine EP '081 and US '223 is expressly and impliedly present in both reference.

Appellants argue that the combination of EP '081 and US '223 cannot teach what it is argued in the rejection to teach. Throwing in US "521, which actually shows one example of the general "type" of vessel used, does nothing to rehabilitate what is not taught by the combination of EP '081 and US '223. The combination of EP '081, US '223 and US '521 cannot teach the claimed invention to one of ordinary skill in the art.

In response to this argument, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir.

1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound dressing gel deliverable from a nozzle for treating cavities comprising natural gelling agent, hydrocolloid, alkylene glycol and water that taught by EP '081, and one having ordinary skill in the art knowing that wound dressing gels can be delivered from an aerosol package as taught by US '223 would have been motivated to replace the delivery means that have a nozzle with an aerosol package, and further use the aerosol package taught by US '521 having inner and outer container separated by pressurized gas, motivated by the teaching of US '521 that the discharged product from such as aerosol has a uniform density and maintained a predetermined physical characteristic all the life of the package. One would reasonably expect having wound dressing gel delivered from an aerosol package having inner container and outer container separated by a pressurized gas wherein the delivered gel will have a uniform density and maintain a predetermined physical characteristic all the life of the package.

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.,* 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine

the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007). A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Appellants argue that one of ordinary skill in the art of wound care would not be expected to be skilled in the non-analogous art of barrier aerosol vessels. US '521 is directed at dispensing foaming compositions such as those used in hair coloring or shaving cream. The user requirements in the hair coloring or shaving cream field noted in '521 broadly concern emptying the container and having a uniform product dispensed. Appellants' invention is concerned with packaging a gel so that the

packaging can be used to dispense more than one dose without compromising the sterility of the remaining doses.

In response to this argument, as discussed above, gel wound dressing delivered from an aerosol container were known at the time of the invention. One having ordinary skill in the art attempting to deliver gel wound dressing having compatible components would have looked at the aerosol area of the art to find an one compartment aerosol container. It is *prima facie* obvious to substitute one functional equivalent for another functionally equivalent aerosol container. In response to applicant's argument that US '521 is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, US '521 is concerned with the problem with which applicants were concerned which is multi-dose sterile aerosol container.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are attached to the Appeal Brief filed August 19, 2009.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Isis A Ghali/
Primary Examiner, Art Unit 1611

Conferees:

/David J Blanchard/
Primary Examiner, Art Unit 1643

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615